LUTATHERA®
(lutetium Lu 177 dotatate)
injection, for intravenous use

Is LUTATHERA a Treatment Option for You?

If your health care professional has told you that your GEP-NET has grown or spread, LUTATHERA may be a treatment option for you. Talk to your health care professional to find out more.

To get some ideas on what to talk to your health care professional about, please take a look at the helpful information inside.

What is LUTATHERA?

LUTATHERA is a prescription medicine used to treat adults with a type of cancer known as gastroenteropancreatic neuroendocrine tumors (GEP-NETs) that are positive for the hormone receptor somatostatin, including GEP-NETs in the foregut, midgut, and hindgut.

IMPORTANT SAFETY INFORMATION

What are some important things to know about the safety of LUTATHERA?

LUTATHERA is associated with some serious safety considerations and, in some cases, these may require your health care provider to adjust or stop your treatment. You should always follow your health care provider's instructions. Safety considerations include:

- **Radiation exposure:** Treatment with LUTATHERA will expose you to radiation, which can contribute to your long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. The radiation will be detectable in your urine for up to 30 days following administration of the drug. It is important to minimize radiation exposure to household contacts consistent with good radiation safety practices as advised by your health care provider.

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Please see additional Important Safety Information throughout and Summary of Important Information on pages 8 and 9.

Medication History

Your health care professional will typically ask about any medications you are currently taking or those you have taken in the past, and your experience with each of them. It may be helpful to write down any medications you are taking, including prescriptions, over-the-counter medicines, and vitamins.

Medication History

Name of Current Medication

Your Experience

Names of Previous Medication(s)

Your Experience

Over-the-Counter Medications

For example, vitamins, supplements, and herbs

You should speak to your health care professional about treatment options that may be appropriate for you.

What do you want out of your next treatment option?

Any other questions or concerns you may have?

IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Bone marrow problems:** Treatment with LUTATHERA increases the risk of myelosuppression, a condition in which bone marrow activity is decreased, resulting in a drop in blood cell counts. You may experience blood-related side effects such as low red blood cells (anemia), low numbers of cells that are responsible for blood clotting (thrombocytopenia), and low numbers of white blood cells (neutropenia). Speak with your health care provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly.

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IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Secondary bone marrow and blood cancers:** Other serious conditions that you may develop as a direct result of treatment with LUTATHERA include blood and bone marrow disorders known as secondary myelodysplastic syndrome and cancer known as acute leukemia. Your health care provider will routinely check your blood cell counts and tell you if they are too low or too high.

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Understanding LUTATHERA

Here is some important information about LUTATHERA that might be helpful to know before talking to your health care professional. We have also provided additional space to write down other questions or thoughts you may want to discuss. If you have additional questions about LUTATHERA, please speak to your health care professional.

What Is LUTATHERA?

- LUTATHERA is a prescription treatment for adults with a type of cancer known as gastroenteropancreatic neuroendocrine tumor (GEP-NET) that has somatostatin hormone receptors
- LUTATHERA is the first and only radioligand therapy (also known as RLT) for GEP-NET, a medicine from a class of drugs called peptide receptor radionuclide therapy (also known as PRRT)
  - LUTATHERA uses radiation to target and damage cells that are positive for the somatostatin hormone receptor, including cancer cells and neighboring cells
- LUTATHERA is given as an intravenous (IV) infusion

Write down any other questions or thoughts about this topic you may have.

IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Kidney problems:** Treatment with LUTATHERA will expose your kidneys to radiation and may impair their ability to work as normal. You may be at an increased risk for kidney problems after LUTATHERA treatment if you already have kidney impairment before treatment. In some cases, patients have experienced kidney failure after treatment with LUTATHERA. Your health care provider will provide you with an amino acid solution before, during, and after LUTATHERA to help protect your kidneys. You should stay well hydrated before, on the day of, and on the day after your treatment. You should urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Your doctor will monitor your kidney function and may withhold, reduce, or stop your LUTATHERA treatment accordingly.

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How Does LUTATHERA Work?

LUTATHERA is believed to work differently from most cancer medications for GEP-NET, with a 2-part approach that specifically targets and enters the cells that have somatostatin receptors, releasing energy in the form of radiation that damages them and nearby cells. In other words, LUTATHERA is a “key” that connects with the “lock” (cells containing somatostatin receptors).

Write down any other questions or thoughts about this topic you may have.

What Were the Clinical Trial Results?

In a clinical trial, 229 people with midgut NETs who received LUTATHERA in combination with 30 mg of long-acting octreotide were compared with those who received 60 mg of long-acting octreotide alone.

In the LUTATHERA group, the relative risk of cancer getting worse or death was reduced by 79% compared with people treated with 60 mg of long-acting octreotide alone.

The most common and most serious side effects of LUTATHERA included: vomiting, nausea, decreased blood cell counts, increased liver enzymes, decreased blood potassium levels, and increased blood glucose.

Write down any other questions or thoughts about this topic you may have.

IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Liver problems:** In clinical studies of LUTATHERA, less than 1% of patients were reported to have tumor bleeding (hemorrhage), swelling (edema), or tissue damage (necrosis) to the liver. If you have tumors in your liver, you may be more likely to experience these side effects. Tell your health care provider right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, unusual tiredness, right upper stomach area (abdomen) pain, confusion, and/or swelling of the stomach area (abdomen). Your health care provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.

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Potential Side Effects

What Are Some Important Things To Know About LUTATHERA?

All prescription medications come with safety considerations. Some considerations you should be aware of before starting LUTATHERA relate to:

- Radiation exposure
- Bone marrow problems
- Secondary bone marrow and blood cancers
- Kidney problems
- Liver problems
- Hormonal gland problems (hormonal crisis)
- Infertility
- Embryo-fetal toxicity

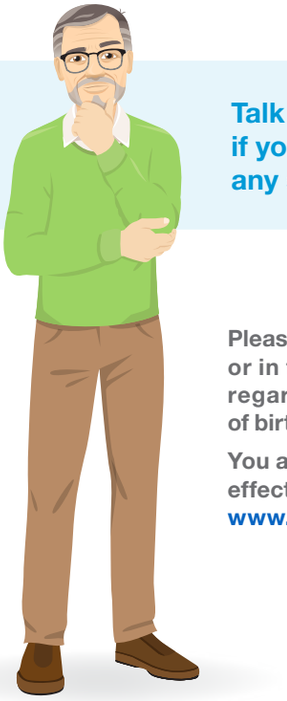
What Side Effects Could I Experience With LUTATHERA?

LUTATHERA may cause side effects. Some of these side effects can be serious, and your health care professional may need to adjust or stop your treatment if you experience any of these. You should always follow the instructions of your health care professional.

In clinical trials, the most common grade 3/4 (severe) adverse reactions occurring with a greater frequency among patients receiving LUTATHERA included:

- Vomiting
- Nausea
- Decreased blood cell counts
- Increased liver enzymes
- Decreased blood potassium levels
- Increased glucose in the bloodstream

Talk to your health care professional if you experience any side effects. There are other possible side effects of LUTATHERA. For more information, and to learn more about LUTATHERA, talk to your health care professional.



Talk to your health care professional if you have concerns or experience any side effects.

Please see additional warnings in this brochure or in the Summary of Important Information regarding pregnancy, breastfeeding, and use of birth control.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Allergic reactions:** Allergic reactions have occurred in people who were treated with LUTATHERA. Notify your health care provider if you develop symptoms of an allergic reaction. Seek emergency help right away for any serious allergic reactions. Symptoms may include trouble breathing or swallowing; raised bumps (hives); rash or itching; and swelling of the face, lips, tongue, throat, or arms.
- **Hormonal gland problems (carcinoid crisis):** During your treatment you may experience certain symptoms that are related to hormones released from your cancer. These symptoms may include flushing, diarrhea, difficulty breathing (bronchospasm), and low blood pressure (hypotension), and may occur during or within the 24 hours after your first LUTATHERA treatment. Your health care provider will monitor you closely. Speak with your health care provider if you experience any of these signs or symptoms.

Please see additional Important Safety Information throughout and Summary of Important Information on pages 8 and 9.

IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Pregnancy warning:** Tell your health care provider if you are pregnant. LUTATHERA can harm your unborn baby. Females should use an effective method of birth control during treatment and for 7 months after the last dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment with LUTATHERA and for 4 months after the last dose.
- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your last dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testes or ovaries over the treatment period falls within the range of exposure in which temporary or permanent infertility may occur.

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Please see additional Important Safety Information throughout.

Summary of Important Information (continued)

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What are the most common side effects of LUTATHERA?

The most common and most serious side effects of LUTATHERA include decreased blood cell counts, increased liver enzymes, vomiting, nausea, increased blood glucose, and decreased blood potassium levels.

Talk to your doctor if you experience any of these side effects. There are other possible side effects of LUTATHERA. For more information and to learn more about LUTATHERA, talk to your doctor or health care provider.

What other medicines may interact with LUTATHERA?

Tell your health care provider if you are taking any other medications. Somatostatin analogs and glucocorticoids may affect how your LUTATHERA treatment works. You should stop taking your long-acting somatostatin analog at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogs up to 24 hours before your LUTATHERA treatment. Avoid repeated high doses of glucocorticoids during treatment with LUTATHERA.

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